Wuxi Jiajian Medical Instrument Co., Ltd
Qinghong Rd., Ehu Town, Xishan District, Wuxi, Jiangsu, China 214116
Tel: 86-510-88745788 | Fax: 86-510-88746629

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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

AUG 16 2013

1. Submission Information:

510(k) Number:	K130768
Date:	June 24th, 2013
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd Qinghong Rd., Ehu Town, Xishan District, Wuxi, Jiangsu, China 214116
Contactor:	Doris Dong (Consultant) Shanghai CV Technology Co., Ltd. Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, China 201600 E-mail: doris_d@126.com / Url: www.ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	Jiajian® CMN Stimulator
Common Name:	Electro-acupuncture Device
Classification Name:	Stimulator, Electro-acupuncture
Product Code:	BWK
Device Class:	Unclassified
Review Panel:	Neurology
Indications for use:	Jiajian® CMN Stimulator is an electro-acupuncture stimulator device, which is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
Device Description:	Jiajian® CMN Stimulator is an electro-acupuncture device for acupuncture therapy, powered by 6 pieces of 1.5V batteries. It is composed of a console and 6 channels of electrode cables with alligator type connectors. Only 3 channels at most could work together on single patient. The console has the operating elements of Wave choosing knob, Frequency adjust knob, Intensity adjust knobs, and Timer. Jiajian® CMN Stimulator does not equip with acupuncture needles. The practitioners should select 510(k) cleared needles (with minimum diameter of 0.30mm and insertion depth of 15mm) for use.
Standards:	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2

3. Substantial Equivalence:

Detailed comparison data is included in Section 9 of "Substantial Equivalence Discussion" of this 510(k) submission.

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A. Basic technological characteristics & Output Specifications, New device VS. Predicate device:

Parameters			New Device	Predicate Device
1	510(k) Number:		K_____	K081943
2	Marketing clearance date:		--	Nov 24th, 2008
3	Device Name		Jiajian® CMN Stimulator	ES-130
4	Manufacturer		Wuxi Jiajian Medical Instrument Co., Ltd	ITO Co., Ltd.
5	Accessories for stimulation mode		Lead wire with alligator type connector (6 sets, in six different colors)	Lead wire with alligator type connector (3 sets, in three different colors)
6	Intended use		Jiajian® CMN Stimulator is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	ES-130 is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
7	Power Source(s)		DC 1.5Vx6, Type R14	DC 9V battery, Type 6F22
	- Method of Line Current Isolation		N/A for DC current	N/A for DC current
	- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)		-- 2μA ≤50μA	-- Not Sated in the manual Not Sated in the manual
8	Number of Output Mode:		3 (continuous wave/ interrupted wave/ Dense-disperse wave)	1 (continuous wave)
9	Number of Output channels:		6 (3 channels at most work together on single patient)	3
10	Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2
11	Waveform		Biphasic	Biphasic
12	Shape		Asymmetric biphasic square wave	Asymmetric biphasic square wave
13	Maximum Output Voltage		24.4V ±10% @500Ω	18.0V±15% @500Ω
14	Maximum Output Current		48.8mA ±10% @500Ω	36.0mA ±15% @500Ω
15	Pulse Duration		200μS ±10%	100μS
16	Frequency		1~100Hz	1~500Hz
17	Net Charge		0μC@500Ω, + and – pulses cancel	0μC@500Ω
18	Maximum Phase Charge, (μC)		17.8μC	7.2μC
19	Maximum Current Density (r.m.s.)		12.6mA/cm^2	25.5mA/cm^2
20	Maximum Average Power Density		0.18W/cm^2	0.24W/cm^2
21.	Burst Mode (i.e. pulse trains):	(a) Pulses per burst	2~420	N/A
		(b) Bursts per second	0.1	
		(c) Burst duration	4.2s	
		(d) Duty Cycle:	0.42	

B. Substantial Equivalence Discussion

Similarities between New device and Predicate Device:	Intended use, input DC power, biphasic square waveform, Net charge, adjustable frequencies and intensity, standards, at most 3 channels of output
Differences between New device and Predicate Device:	The two devices have different weight, dimensions, output pulse width, frequency range; The predicate device has a battery level check button, while the new device auto shut when the input power is less than 8.1V; The new device outputs 3 modes of waveforms (continuous wave, interrupted wave & Dense-disperse wave), while the predicate device has only 1 mode of continuous wave

Conclusion:

The new device and the predicate device have same intended use, input DC power, biphasic square waveform, zero net charge, complied standards, adjustable frequency and intensity.

The differences between the two devices are analyzed as following:

① Interrupted wave (Burst Mode) and Dense-disperse wave: The new device has burst mode which is composed of a continuous train of impulses with a small pause in between while the predicate device has continuous train of impulses. The Dense-disperse wave of new device is composed of a alternating frequency. But the basic characteristics of the Interrupted wave (Burst Mode) and Dense-disperse wave of the proposed device are consistent with the continuous wave, so this difference does not raise new types of questions of safety or effectiveness.

② Maximum output voltage, maximum output current, output pulse width, frequency range:

The new device has higher maximum output voltage and current than Predicate device. The output pulse width of new device is higher than the Predicate device while the frequency range is lower than the Predicate device.

Because the physiological effectiveness of stimulation is primarily dependent on delivered charge, and the maximum phase charge per pulse of the new device is a little higher than the Predicate device, so it can achieve the effectiveness. And the maximum output Charge is within the safety limit.

Therefore this difference does not raise new types of questions of safety or effectiveness.

③ Maximum power density, total maximum RMS current passed through the body:

Maximum power density is smaller than the predicate device. Though the new device has 6 channels of output, only 3 channels at most could be used on single patient, and the total maximum RMS current of the new device passed through the body is smaller than the predicate device. So the differences would not raise new safety concerns.

To sum up, the new device Jiajian® CMN Stimulator is substantially equivalent to Predicate device of ES-130 (K081943).

4. Safety and Effectiveness of the device

Jiajian® CMN Stimulator was tested and found to meet the safety standards of:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
* IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators; and
* IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

The output lead wires with Alligator type connectors used for Jiajian® CMN Stimulator were tested and found to comply with the safety standards of:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

The device was also tested basis on reduced battery level, and was found that the stimulus parameters were not significantly affected (less than ±10%).

The conclusion drawn from the testing is that the device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Wuxi Jiajian Medical Instrument Co., Ltd
c/o Ms. Doris Dong
Shanghai CV Technology Co., Ltd
Room 1706, No. 128 Songle Rd
Songjiang Area
Shanghai, China 201600

Re: K130768
Trade/Device Name: Jiajian CMN Stimulator
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: BWK
Dated: June 27, 2013
Received: July 16, 2013

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130768

Device Name: Jiajian® CMN Stimulator

Indications For Use:

Jiajian® CMN Stimulator is an electro-acupuncture stimulator device, which is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130768